

TAIZHOU XINGMING PHARMACEUTICAL CO., LTD.

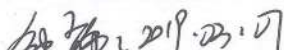
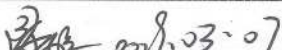
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CERTIFICATE OF ANALYSIS

SOR-ZL232-05

NAME OF PRODUCT 品名: CLOZAPINE 氯氮平	
BATCH NO 批号: C104-190202	MFG DATE 生产日期: 2019.02.16
QUANTITY 数量: 504.3kg	TEST DATE 检验日期: 2019.02.25
SOURCE 来源: 03 车间	REPORT DATE 报告日期: 2019.03.07
RETEST DATE 复验期: 2022.02.15	NUMBER OF COA 报告单号: 1902-014
STANDARDS 标准依据: EP9.0	

ITEMS 项目		STANDARDS 标准	RESULTS 结果
Appearance 外观		Yellow crystalline powder 黄色结晶性粉末	Conforms 符合规定
Identification 鉴别			
-IR spectrum 红外光谱		Same as Ref.Standard 与对照品一致	Conforms 符合规定
-Melting point 熔点		182-186℃	183.0-185.5℃
Loss on drying 干燥失重		≤0.5%	0.07%
Sulphated ash 硫酸灰分		≤0.1%	0.04%
Heavy metals 重金属		≤0.001%	<0.001%
Residual solvents (GC) 残留溶剂			
-Toluene 甲苯		≤890ppm	ND 未检出
-Ethanol 乙醇		≤5000ppm	377.4ppm
Related substances (HPLC) 相关物质			
- impurity A 杂质 A		≤0.1%	ND 未检出
- impurity B 杂质 B		≤0.2%	0.01%
- impurity C 杂质 C		≤0.3%	0.01%
- impurity D 杂质 D		≤0.2%	0.02%
-Largest unspecified impurity 最大未知杂质		≤0.10%	0.01%
-Total impurities 总杂质		≤0.6%	0.06%
Assay (on dry basis) 含量 (按干燥品计)			
-Non-aqueous titration 非水滴定		99.0~101.0%	99.9%
结论 Conclusion	The above mentioned product conforms to Standards.		
Position	Reporter	Checker	Approver
Signature/Date	 2019.03.07	 2019.03.07	 2019.03.07